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JUL 10 2007

Amy J. Hoffman  
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221 Main Street North, Suite 200  
Stillwater, MN 55082

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,571,182  
Filed: December 20, 2006

**NOTICE OF INFORMALITIES**

The above-identified application for patent term extension is considered informal because the application does not comply with certain provisions of 37 C.F.R. 1.740.

The following requirements have not been complied with:

(1) 37 C.F.R. 1.740(a)(1) requires a complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics.

Here, Applicant has not identified the product other than to state that the approved product is an Injectable Urethral Bulking Agent known as Macroplastique® Implants.

(2) 37 C.F.R. 1.740(a)(6) requires a complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration.

Here, there is no identification of the correct issue date.

(3) 37 C.F.R. 1.740(a)(6) requires a copy of any disclaimer, certificate of correction, receipt of maintenance fee payment or reexamination certificate issued in the patent

Here there is no copy of the terminal disclaimer filed in the prosecution of U.S. Patent No. 5,571,182, which disclaims over U.S. Patent No. 5,258,028.

(4) 37 C.F.R. 1.740(a)(13) requires a statement that applicant acknowledges a duty to disclose to the Director of the United States Patent and Trademark Office and the Secretary of Health and Human Services or the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought.

Although Applicant have made a statement acknowledging their duty of disclosure, Applicants have not disclosed the second patent term extension application filing for the same product, Macroplastique® Implants, which was filed in U.S. Patent No. 5,571,182.

Applicant has **TWO MONTHS** from the date of this letter in order to file a complete application. Extensions of time under 37 CFR 1.136 are available. Failure to respond will result in the application for patent term extension being processed as an informal application. Alternatively, applicant may have the holding of informality reviewed as set forth in 37 CFR 1.740(c).

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail:                   Commissioner for Patents  
                                 Mail Stop Hatch-Waxman PTE  
                                 Washington, D.C. 20231

By FAX:                   (571) 273-0100  
                                 Attn: Office of Patent Legal Administration

Telephone inquiries related to this notice should be directed to the undersigned at (571) 272-7755.

  
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Mary C. Tilly  
legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc:                           Office of Regulatory Policy                           Re: Macropластique® Implants  
                                 HFD-7  
                                 5600 Fishers Lane (Rockwall II Rm 1101)  
                                 Rockville, MD 20857  
  
                                 Attn: Beverly Friedman